Reconsideration of the above-identified application is respectfully requested in view of the following remarks:

REMARKS

Claims 1 and 5 have been amended to recite that the oral medicinal composition is an "aqueous" composition. Support for this limitation is explicitly provided at page 13, lines 12-15 of the specification. Further, claims 1 and 5 have been amended to state that the active ingredient is "for internal use" as set forth at page 1, line 13 of the specification and similar language throughout the application. Further, claims 1 and 5 have been limited to state that the composition is foamed with air as explicitly set forth at page 13, lines 8-11. Finally, claim 1 has been amended to state the foam composition is capable of being reliquified as set forth at page 5, line 19.

New claims 9 and 13 are supported at page 8, lines 8-9 of the specification. New claims 10 and 11 are believed supported at page 9, lines 2-4 and Example 3, formulations 7-9. Claim 12 is a new claim clearly supported at page 10 of the specification.

Claims 1-3 and 5-7 have been rejected under 35 USC 102(b) as being anticipated by Saferstein et al. (U.S. 6,086,856). The Examiner states that the claims are drawn to an oral formulation comprising a medicament and a foaming agent and that the claims also recite a method of administration. The primary reference is described as disclosing a foaming oral composition delivered via an air-driven foaming device container and discloses among other foaming agents polyethylene glycol, polysorbate and sodium lauryl sulfate. The rejection is respectfully traversed.

To provide anticipation of the claims, the Examiner must find each and every limitation of the claims contained within the four corners of the applied reference.

Saferstein et al. is concerned with an oral hygiene formulation which comprises mouthwashes, rinses, and dentifrices. Thus, the applied reference is concerned with medicinal compositions which are not for internal use, as now claimed. In fact, the reference at column 4, lines 35-46 clearly states that the aerated foams as disclosed therein are particularly useful since a smaller total quantity of the ingredients are in the mouth at one time during a given treatment period. This is advantageous since many of the ingredients are harmful if ingested. On the other hand, the claimed composition and method are directed to a composition and method of application of same wherein the active ingredient is for internal use. Thus, the present invention is directed to a composition and method of use in which the active ingredient is intended to be swallowed. The formation of the foam allows the medicinal composition to be passed through the throat relatively easily and without pain to the user. Many persons have a difficulty in swallowing solids or slugs of liquid compositions. The foam composition of the present invention is useful since the composition can be passed through the throat and then reliquified for internal use. Accordingly, since the applied reference does not teach an active ingredient which is useful for internal use, the patent cannot anticipate claim 1 directed to the composition and claim 5 directed to the method of administering the composition and the claims dependent thereon. Withdrawal of the rejection based on anticipation over Saferstein et al. is respectfully requested.

Claims 1, 2, 5, and 6 have been rejected under 35 USC 102(b) as being anticipated by Mackles et al. (WO 86/05392). The primary reference is described as disclosing an aerosol foaming composition comprising medicaments and foaming agents. The Examiner states that since the formulation is in aerosol form, the composition further

comprises propellants and is administered via an aerosol container. The rejection is respectfully traversed.

Again, for anticipation, the primary reference must teach each and every limitation of the claims. Claims 1 and 5 now recite that the oral composition is an aqueous oral medical composition. The primary reference discloses an anhydrous foam. Further, the active ingredients are solid materials which are not reliquified. Still further, the primary reference uses hydrocarbon propellants and the like, and does not teach the use of air to form the foam as in the claimed invention. Accordingly, WO 86/05392 does not anticipate claims 1, 2, 5, and 6, and it is respectfully requested that the rejection be withdrawn.

Claims 4 and 8 have been rejected under 35 USC 103(a) as being unpatentable over Saferstein et al (U.S. 6,086,856). The Examiner states that Saferstein et al. discloses an oral foaming composition comprising polyethylene glycol, polysorbate, and sodium lauryl sulfate. The Examiner states that the reference, however does not disclose the exact mixtures of claims 4 and 8, although a mixture of sodium lauryl sulfate and polysorbate is provided in example 3. The Examiner is of the position that the combination of foaming agents as recited in claims 4 and 8 would be well within the level of skill in the art. The rejection is respectfully traversed.

First, Saferstein et al. is not concerned with the composition of the present invention which is for internal use. The Saferstein et al. composition is for application to the oral cavity, which is then expectorated therefrom. Accordingly, Saferstein does not disclose the basic composition and process of the present invention. Specifically, applicants have further found that the combinations of foaming agents as set forth in claims 4 and 8 can be used to accurately control the sustainability of the foam before it is

liquefied. Saferstein et al. does not include any discussion of controlling the retention time of the foam, and clearly does not disclose the particular combinations of foaming agents which are claimed and which can be used to control the foaming retention. The Examiner is kindly invited to the examples in the specification where combinations of sodium lauryl sulfate and polyethylene glycol and polysorbate 80 and polyethylene glycol have been used and the amounts thereof varied to control the duration of the foam. In as much as Saferstein et al. does not describe the use of the foaming agents to control the retention of the foam, it is believed that the rejection based on obviousness is improper.

In view of the above remarks, it is believed that claims 1-13 patentably distinguish over the art of record, and applicants respectfully solicit favorable actions on these claims.

Respectfully submitted,

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